

What is claimed is:

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B1

- 5 1. A polynucleotide vaccine composition comprising a nucleic acid sequence that encodes an influenza virus M2 antigen, wherein said nucleic acid sequence is not present in a recombinant viral vector.
2. The composition of claim 1 wherein the nucleic acid sequence is present in a plasmid vector.
- 10 3. The composition of claim 1 wherein the nucleic acid sequence encodes an influenza virus M2 polypeptide.
- 15 4. The composition of claim 3 wherein the influenza virus M2 polypeptide comprises an amino acid sequence selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, and hybrids or combinations thereof.
- 20 5. The composition of claim 1 further comprising a second nucleic acid sequence that encodes an influenza virus antigen derived or obtained from an influenza virus polypeptide selected from the group consisting of the nucleoprotein (NP), neuraminidase (NA), hemagglutinin (HA), polymerase (PB1, PB2, PA), matrix (M1), and non-structural (M2, NS1, NS2) gene products.
- 25 6. The composition of claim 1 further comprising an adjuvant component.
7. The composition of claim 6 wherein said adjuvant component is present in the composition in the form of a nucleic acid sequence.

8. The composition of claim 7 wherein said adjuvant component is a CpG sequence.

9. The composition of claim 7 wherein said adjuvant component is a further  
5 nucleic acid sequence that encodes a polypeptide adjuvant.

10. The composition of claim 6 wherein said adjuvant component is present in the composition in a form other than a nucleic acid sequence.

10 11. The composition of claim 10 wherein said adjuvant component is present in the composition in the form of a polypeptide.

12. The composition of claim 10 wherein said adjuvant component is present in the composition in the form of a lipid.

15 13. The composition of claim 10 wherein said adjuvant component is present in the composition in the form of a non-protein hormone or an analog thereof.

20 14. The composition of claim 10 wherein the adjuvant component is present in the composition in the form of a vitamin or an analog thereof.

15. The composition of claim 10 wherein the adjuvant component comprises monophosphoryl lipid A.

25 16. The composition of claim 10 wherein the adjuvant component comprises a saponin or a derivative thereof.

17. The composition of claim 16 wherein the adjuvant component comprises Quil-A.

5 18. The composition of claim 1 further comprising a pharmaceutically acceptable excipient or vehicle.

19. The composition of claim 1 wherein said composition is in particulate form.

10 20. The composition of claim 19 wherein the nucleic acid sequence is coated onto a core carrier particle.

21. The composition of claim 20 wherein the core carrier particle has an average diameter of about 0.1 to about 10 $\mu$ m.

15 22. The composition of claim 20 wherein the core carrier particle comprises a metal.

23. The composition of claim 22 wherein the metal is gold.

20 24. A particle acceleration device suitable for use in a nucleic acid immunization technique, wherein said device is loaded with a particulate vaccine composition as defined in claim 19.

25 25. The composition of claim 1 further comprising a transfection facilitating agent.

26. A method for eliciting an immune response against an influenza virus in a subject, the method comprising administering the vaccine composition of claim 1 to the subject, whereby upon introduction to the subject, the nucleic acid sequence is expressed to provide the influenza virus M2 antigen in an amount sufficient to elicit said immune response.

27. The method of claim 26 wherein the vaccine composition is combined with a pharmaceutically acceptable vehicle and administered to the subject in the form of a liquid.

28. The method of claim 26 wherein the vaccine composition is administered directly into skin or muscle tissue.

29. The method of claim 26 wherein the vaccine composition is administered to mucosal tissue.

30. The method of claim 26 wherein the vaccine composition is administered by inhalation.

31. The method of claim 26 wherein the vaccine composition is administered topically.

32. The method of claim 26 wherein the vaccine composition is administered to the subject in particulate form.

*Sub B2*

33. The method of claim 26 wherein the nucleic acid sequence is coated onto a core carrier particle and administered to the subject using a particle-mediated delivery technique.

5 34. The method of claim 26 wherein the vaccine composition further comprises an adjuvant component.

35. The method of claim 26 further comprising the step of administering a second vaccine composition to the subject.

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36. The method of claim 35 wherein the second vaccine composition is an anti-influenza vaccine selected from the group consisting of a whole virus vaccine, a subunit vaccine, a split vaccine, a nucleic acid vaccine, and any combination thereof.

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37. The method of claim 35 wherein the second vaccine composition is administered to the subject in a boosting step.

38. The method of claim 35 wherein the vaccine composition of claim 1 and the second vaccine composition are administered to the same site in the subject.

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39. The method of claim 35 wherein the vaccine composition of claim 1 and the second vaccine composition are administered concurrently.

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40. The method of claim 35 wherein the vaccine composition of claim 1 and the second vaccine composition are combined to provide a single composition.

Sub B3

41. A method for using an influenza virus M2 antigen to induce an immune response in a subject, said method comprising:
- (a) obtaining a nucleic acid sequence encoding the M2 antigen;
  - (b) providing an expression cassette by linking the nucleic acid sequence to regulatory sequences such that the nucleic acid sequence is operatively linked to control sequences that direct expression of the M2 antigen when introduced into tissue of the subject, wherein said expression cassette is not present in a recombinant viral vector; and
  - (c) administering the expression cassette to tissue of the subject.
42. The method of claim 41 wherein the expression cassette is present in a plasmid vector.
43. The method of claim 41 wherein the nucleic acid sequence encodes an influenza virus M2 polypeptide.
44. The method of claim 41 wherein the influenza virus M2 polypeptide comprises an amino acid sequence selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, and hybrids or combinations thereof.
45. The method of claim 42 wherein the plasmid vector is administered directly into skin or muscle tissue of the subject.
46. The method of claim 45 wherein the plasmid vector is administered to the subject in particulate form.

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*Sub B4* 47. The method of claim 45 wherein the plasmid vector is coated onto a core carrier particle and administered to the subject using a particle-mediated delivery technique.

5 48. The method of claim 41 wherein the subject is human.

*Sub B5* 49. A method of eliciting a protective immune response in a subject, said method comprising transfecting cells of the subject with a polynucleotide encoding an influenza virus M2 antigen, wherein said transfecting is carried out under conditions that permit expression of said antigen within the subject, said polynucleotide is not present in a recombinant viral vector, and said expression is sufficient to elicit a protective immune response against an influenza virus.

10 50. The method of claim 49 wherein the transfecting step is carried out *in vivo* using a particle-mediated transfection technique.